Initial Approval: March 11, 2009
Revised Dates: October 1~~4~~4, 20~~17~~20, October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Monoamine Depletors (VMAT2 Inhibitors)

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.
~~**PROVIDER GROUP** Pharmacy~~

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.~~The following drug requires prior authorization:~~

~~Deutetrabenzine~~Deutetrabenazine (Austedo®™)
Tetrabenazine (Xenazine®)
Valbenazine (Ingrezza®)

GENERAL CRITERIA FOR INITIAL ~~APPROVAL FOR TETRABENAZINE~~PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Must be prescribed by or in consultation with a neurologist or psychiatrist.
- For the treatment of tardive dyskinesia (TD):
  - The prescriber must provide the patient's baseline AIMS rating evaluation.[4]
- For the treatment of chorea associated with Huntington's disease:
  - Patient must NOT be suicidal or have a history of untreated or inadequately treated depression.[1,2]
  - Prescriber must provide the patient's baseline Total Chorea Score.[5]
- If the request is for tetrabenazine and the dose is greater than (>) 50 mg daily, the ~~patient~~prescriber must provide CYP2D6 genotyping test results confirming~~ be genotyped as~~ the patient is an~~an~~ intermediate or extensive metabolizer~~ of CYP2D6~~.[3]

LENGTH OF APPROVAL (INITIAL): 6 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- For the treatment of TD, patient has an improvement (reduction) in AIMS scores of at least 3 points from baseline.[8]
- For the treatment of chorea associated with Huntington's disease, patient has an improvement (reduction) in Total Chorea Score of at least 2 points from baseline.[5]
- Must not exceed dosing limits listed in Table 1.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

-LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved age and dosing limits for Monoamine Depletors (VMAT2 Inhibitors)[1-3]

Agents	Indication(s)	Age	Dosing Limits
Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors			
Deutetrabenazine (Austedo®)	Chorea associated with Huntington's disease Tardive dyskinesia	≥ 18 years	48 mg orally daily
Tetrabenazine (Xenazine®)	Chorea associated with Huntington's disease	≥ 18 years	50 mg orally daily Intermediate or extensive metabolizers of CYP2D6: 100 mg orally daily
Valbenazine (Ingrezza®)	Tardive dyskinesia	≥ 18 years	80 mg orally daily

- ~~For doses ≤ 50 mg per day:~~
  - ~~Diagnosis of chorea associated with Huntington's disease~~
  - ~~Patient must be 18 years of age or older~~
  - ~~Prescribed by a neurologist~~
  - ~~Must NOT have any of the following:~~
    - ~~Hepatic impairment~~
    - ~~Be taking a monoamine oxidase inhibitor (MAOI), reserpine (at least 20 days should elapse after stopping reserpine before starting tetrabenazine), or another VMAT2 inhibitor~~
    - ~~Suicidal, or untreated/inadequately treated depression~~
- ~~For doses > 50 mg per day:~~
  - ~~Must meet all of the above stated criteria for less than 50mg per day~~
  - ~~Patient must be genotyped for CYP2D6 and must be extensive or intermediate metabolizer~~

~~**CRITERIA FOR INITIAL APPROVAL FOR DEUTETRABENAZINE:** (must meet all of the following)~~

- ~~Must meet one of the following:~~
  - ~~Diagnosis of chorea associated with Huntington's disease~~
  - ~~Diagnosis of tardive dyskinesia~~
- ~~Patient must be 18 years of age or older~~
- ~~Prescribed by a neurologist~~
- ~~Must NOT have any of the following:~~
  - ~~Hepatic impairment~~
  - ~~Be taking a monoamine oxidase inhibitor (MAOI), reserpine (at least 20 days should elapse after stopping reserpine before starting deutetrabenazine), or another VMAT2 inhibitor~~
  - ~~Suicidal, or untreated/inadequately treated depression~~
- ~~Dose must not exceed 48 mg per day~~

~~**CRITERIA FOR INITIAL APPROVAL FOR VALBENAZINE:** (must meet all of the following)~~

- ~~Diagnosis of tardive dyskinesia~~
- ~~Patient must be 18 years of age or older~~
- ~~Prescribed by a neurologist~~
- ~~Must NOT have any of the following:~~
  - ~~Hepatic impairment~~
  - ~~Be taking a monoamine oxidase inhibitor (MAOI), reserpine (at least 20 days should elapse after stopping reserpine before starting valbenazine), or another VMAT2 inhibitor~~
  - ~~Suicidal, or untreated/inadequately treated depression~~
- ~~Dose must not exceed 80 mg per day~~

~~**LENGTH OF APPROVAL:** 6 months~~

~~**CRITERIA FOR RENEWAL** (must meet all of the following):~~

- ~~Must meet one of the following:~~
  - ~~Diagnosis of chorea associated with Huntington's disease and have a reduction in Total Chorea Score of at least 5 points from baseline~~
  - ~~Diagnosis of tardive dyskinesia and have a reduction in AIMS or DISCUS score of at least 3 points from baseline~~

~~**LENGTH OF APPROVAL:** 12 months~~

References

1. Austedo (deutetrabenazine) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc; June 2020. ~~Accessed on September 28, 2020.~~
2. Ingrezza (valbenazine) [prescribing information]. San Diego, CA: Neurocrine Biosciences, Inc; April 2020. ~~Accessed on September 28, 2020.~~
3. Xenazine (tetrabenazine) [prescribing information]. Deerfield, IL: Lundbeck; November 2019. ~~Accessed on September 28, 2020.~~
4. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: Treatment of tardive syndromes: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology Jul 2013;81(5):463-469. Available at http://n.neurology.org/content/81/5/463 . Accessed on September 10, 2020.
5. Armstrong MJ, Miyasaki JM. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology Aug 2012;79(6):597-603. Available at http://n.neurology.org/content/79/6/597. Accessed on September 10, 2020.
6. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington, VA: American Psychiatric Association, 2013. Available at http://cdn.website-editor.net/30f11123991548a0af708722d458e476/files/uploaded/DSM%2520V.pdf. Accessed on September 10, 2020.
7. American Psychiatric Association: Practice Guideline for the Treatment of Patients with Schizophrenia, Third Edition. Washington, DC: American Psychiatric Association, 2020. Available at http://psychiatryonline.org/doi/pdf/10.1176/appi/books.9780890424841. Accessed on September 10, 2020.
8. Stacy M, Sajatovic M, Kane JM, et al. Abnormal involuntary movement scale in tardive dyskinesia: Minimal clinically important difference. Mov Disord 2019 Aug;34(8):1203-1209. Available at

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6772010/~~http://ncbi.nlm.nih.gov/pmc/articles/PMC6672010/~~. Accessed on September 10, 2020.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
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